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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,376	08/31/2001	Pedro A. Navarro Acevedo	35718/237948(5718-140)	2174

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/945,376	Applicant(s) ACEVEDO ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 18-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5/30/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-38 are pending.
2. This application contains claims 18-38 drawn to an invention nonelected in Paper No. 8. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The title of the invention is still not descriptive of the instant invention, which is a pathogen-activated promoter, plants transformed with constructs comprising it and methods of using it to express heterologous nucleic acids. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

In the response filed 30 May 2003 Applicant urges that the title has been amended (response pg 13). This is not found persuasive because the instantly claimed invention is not drawn to the major latex protein gene.

4. The abstract remains not descriptive of the instant invention, which is a pathogen-activated promoter, plants transformed with constructs comprising it and methods of using it to express heterologous nucleic acids. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

In the response filed 30 May 2003 Applicant urges that the abstract has been amended (response pg 13). This is not found persuasive because the instantly claimed invention is not drawn to the major latex protein gene.

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5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The objection to claims 1-2, 5, 9, 13 and 17 because of informalities is withdrawn in light of Applicant's amendments.

Claim Rejections - 35 USC § 112

7. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 February 2003. Applicant's arguments filed 30 May 2003 have been fully considered but they are not persuasive.

Applicant urges that given the full-length sequence for the promoter, one of skill in the art would be able to make and use the promoter (response pg 14).

This is not found persuasive. The specification also fails to provide evidence that SEQ ID NO:3 functions as a promoter. The claims are also drawn to promoters that hybridize to SEQ ID NO:3 and the specification teaches no such promoter.

Applicant urges that guidance for hybridization is provided on pg 8-10 and guidance for primer design and their use is on pg 20-22 (response pg 14-15).

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This is not found persuasive. The guidance provided is only general and not specific to the hybridization with the instant sequence. The specification also does not teach any promoter that hybridizes to SEQ ID NO:3.

8. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 February 2003. Applicant's arguments filed 30 May 2003 have been fully considered but they are not persuasive.

Applicant urges that they have given clear guidance for hybridization conditions and requirements and have amended the claims to specify those conditions (response pg 15).

This is not found persuasive. The specification does not describe the structural features of any promoters that hybridize to SEQ ID NO:3.

9. Claims 1-17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 February 2003. Applicant's arguments filed 30 May 2003 have been fully considered but they are not persuasive.

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Claim 1, part (c), claim 5, part (c), claim 9, part (c), and claim 13, part (c) are indefinite in their recitation of "stringent conditions". It is unclear what conditions are considered stringent. Thus, the metes and bounds of the claimed nucleic acid are unclear.

Applicant urges that the claim now recites the stringency conditions (response pg 16).

This is not found persuasive because the hybridization and wash times are not recited.

Claim Rejections - 35 USC § 102

10. Claims 1-5, 8-9, 12-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Stalker et al (WO 98/30698). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 February 2003. Applicant's arguments filed 30 May 2003 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to remove reference to promoters comprising 30 contiguous nucleotides of SEQ ID NO:3. Applicant also urges that Stalker et al do not teach a major latex protein promoter (response pg 16).

This is not found persuasive because given that the hybridization and wash times are not recited and given that Stalker et al teach a promoter comprising 41 contiguous nucleotides of SEQ ID NO:3, that promoter would hybridize to SEQ ID NO:3 under the recited conditions.

11. Claims 1-5, 8-9, 12-13 and 16-17 rejected under 35 U.S.C. 102(e) as being anticipated by Perera et al (US Patent 6,462,257, filed 1 June 1999). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 February 2003. Applicant's arguments filed 30 May 2003 have been fully considered but they are not persuasive.

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Applicant urges that the claims have been amended to remove reference to promoters comprising 30 contiguous nucleotides of SEQ ID NO:3. Applicant also urges that Perera et al does not teach a major latex protein promoter (response pg 16).

This is not found persuasive because given that the hybridization and wash times are not recited and given that Perera et al teach promoters comprising 37 contiguous nucleotides of SEQ ID NO:3, that promoter would hybridize to SEQ ID NO:3 under the recited conditions.

Claim Rejections - 35 USC § 103

12. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perera et al (US Patent 6,462,257, filed 1 June 1999) in view of Gordon-Kamm et al (1990, Plant Cell 2:603-618). The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 February 2003. Applicant's arguments filed 30 May 2003 have been fully considered but they are not persuasive.

Applicant urges Perera et al does not teach a major latex protein promoter of SEQ ID NO:3 (response pg 16).

This is not found persuasive because the claims are not solely drawn to promoters of SEQ ID NO:3.

Applicant urges that Gordon-Kamm et al do not teach, disclose or suggest a major latex protein promoter of SEQ ID NO:3 (response pg 17).

This is not found persuasive because the claims are not solely drawn to promoters of SEQ ID NO:3.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant urges that the references cannot be combined to motivate one of skill in the art to express a heterologous nucleic acid in a plant using the promoter of SEQ ID NO:3 or using a promoter that hybridizes to SEQ ID NO:3 (response pg 17).

This is not found persuasive because given that the hybridization and wash times are not recited and given that Perera et al teach promoters comprising 37 contiguous nucleotides of SEQ ID NO:3, that promoter would hybridize to SEQ ID NO:3 under the recited conditions.

One of ordinary skill in the art would have been motivated to combine the references because of the economic importance of maize (Gordon-Kamm et al, pg 603, right column paragraph 1) and because of the desirability of expressing heterologous nucleic acids in specific plant tissues (Perera et al, column 2, line 54, to column 3, line 6)

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
December 5, 2003



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER